

REMARKS

The applicant appreciates the Examiner's thorough examination of the application and requests reexamination and reconsideration of the application in view of the following remarks.

The applicant acknowledges the Examiner's indication that claims 19, 41-44, and 60 have also been withdrawn from the subject application, and that claims 1-11, 17, 18, 20-34, 45-52, 58, 59, and 61-66 are currently pending in the application. The applicant also appreciates the Examiner's indication that claims 21-34 are allowed, upon correction of a typographical error in claim 23. The applicant has amended claim 23 as suggested by the Examiner to overcome the objection of claim 23. Accordingly, claims 21-34 are in condition for allowance.

The Examiner rejects claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The applicant has amended claim 7 to clarify the claim. Accordingly, the applicant submits that the § 112 rejection has been overcome.

The Examiner also objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner states that the subject matter of claims 62 and 63 are not described in the specification. To advance prosecution of the subject application, claims 62 and 63 have been cancelled from the application.

The Examiner rejects claims 1-3, 8-10, 17, 18, 20, 45-47, 49-51, 58, 59, 61, 64, and 65 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,044,401 to Guiset, and claims 4, 48, and 62 under 35 U.S.C. § 103(a) as unpatentable over Guiset.

The Examiner alleges that Guiset discloses a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising artificially increasing pressure (by mere

placement of balloon 27 or inflation by reservoir 23) which reduces or inhibits natural renal function and thereafter reducing pressure.

Guiset is directed to an artificial bladder for use by a person suffering impairments to their bladder to provide for inducing independent urination. The bladder of Guiset consisting of an enclosing wall 1 forming a cavity 2, two upper apertures 3 connected to ureters 7, a lower aperture coupled to urethra 12, and sphincters which are normally open at the upper apertures 3 and closed at lower aperture 4 which are capable of closing and opening at will when it is desired to induce urination. *See* Col. 21 line 28-Col. 3, line 8 of Guiset. The bladder of Guiset also includes a reservoir 23 outside of the enclosing wall 1, a passage 28, and a balloon 27 positioned inside the cavity 2. *See* Col. 3, line 40-Col. 4, line 7, and Fig. 1 of Guiset.

In operation, when the volume of urine in the cavity 2 of Guiset approaches the cavity's maximum volume, balloon 27 evacuates fluid 24 into the reservoir 23 which warns the person that the bladder is filling. The person then presses on the reservoir 23 which forces fluid into the balloon 27 which increases pressure in the cavity 2. Once the pressure in the cavity becomes greater than the threshold pressure of the lower collar, the lower aperture 4 opens, and the urine drains through the lower aperture 4. When cavity 2 is empty, the fluid 24 evacuates from balloon 27 and returns to the reservoir 23. *See* Col. 5, lines 3-35 of Guiset.

Independent claim 1 of the subject application is directed to a method to protect a kidney in a mammalian patient comprising artificially increasing pressure in a urinary tract of at least one kidney of the patient, reducing a renal function of the kidney by maintaining the increased pressure, and reducing the pressure in the urinary tract to increase the renal function above the reduced renal function.

Guiset fails to disclose reducing a renal function of the kidney by maintaining the

increased pressure as claimed by the applicant. As noted above, the pressure on the bladder of Guiset increases as the balloon 27 fills with fluid. However, once the pressure in the bladder is greater than a predetermined threshold, the lower aperture opens which allows the urine to drain. Then, the pressure in the cavity decreases as the balloon evacuates the fluid.

Nowhere does Guiset disclose increasing the pressure in a urinary tract, and then maintaining the increased pressure. Once the predetermined threshold pressure in the cavity of Guiset has been exceeded, the urine drains and the pressure in the cavity decreases. The pressure in the cavity of Guiset peaks as it exceeds the threshold pressure, and then begins to immediately decrease as the urine drains. Thus, the applicant submits that Guiset clearly fails to disclose that the increased pressure is maintained as claimed by the applicant.

Additionally, Guiset fails to disclose reducing a renal function of the kidney by maintaining the increased pressure as claimed by the applicant. Nowhere does Guiset disclose anything regarding the operation of the kidneys. Guiset is solely directed to an artificial bladder to enable a patient to urinate. As Guiset fails to disclose maintaining the increased pressure, Guiset also fails to disclose reducing a renal function of the kidney as claimed by the applicant.

Accordingly, independent claim 1 and its dependent claims are patentable over Guiset for at least the above reasons.

Independent claim 45 of the subject application is directed to a method to inhibit a natural function of a kidney of a patient during surgery by artificially increasing a pressure in a urinary tract of at least one kidney of the patient, performing the surgery on the patient, and reducing pressure in the urinary tract of the kidney to substantially a pressure level existing before the pressure was artificially increased.

As noted above, Guiset discloses increasing the pressure in the cavity over a threshold

pressure, at which point the urine drains from the cavity and the pressure in the cavity decreases. However, nowhere does Guiset disclose increasing the pressure in the cavity, performing surgery on the patient, and then reducing the pressure as claimed by the applicant. Guiset only increases the pressure in the cavity until the threshold pressure is exceeded, at which point the urine drains from the cavity and the pressure decreases. Guiset fails to disclose performing surgery on the patient at all, let alone between increasing and decreasing the pressure in the cavity.

Accordingly, as Guiset fails to disclose performing surgery on the patient as claimed by the applicant, independent claim 45 and its dependent claims are patentable over Guiset.

The Examiner rejects claims 1-3, 5, 6, 8-11, 17, 18, 20, 45-47, 49-52, 58, 59, 61, and 63-66 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,682,555 to Cioanta *et al.*, and claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Cioanta *et al.* in view of Induced hypotension and blood loss during surgery to Donald.

Cioanta *et al.* is directed to methods for treating the prostate. Cioanta *et al.* discloses a treatment catheter 20 which includes an axially extending shaft 21, a bladder anchoring balloon 52, a treatment balloon 15, and a lower blocking balloon 22. Catheter 20 also includes a urine discharge port 20e that is in fluid communication with a urine discharge or drainage channel 52d that allows urine to drain from the bladder through the catheter 20 while the catheter is in the subject. *See* Col. 2, lines 15-44, and Figs. 1A and 10A of Cioanta *et al.*

Independent claims 1 and 45 of the subject application include the feature of artificially increasing pressure in a urinary tract of at least one kidney of the patient. The Examiner alleges that the inflation of balloon 15 or 52 of Cioanta *et al.* artificially increases the pressure in the urinary tract and refers to Fig. 10B of Cioanta *et al.*, which is reproduced below:

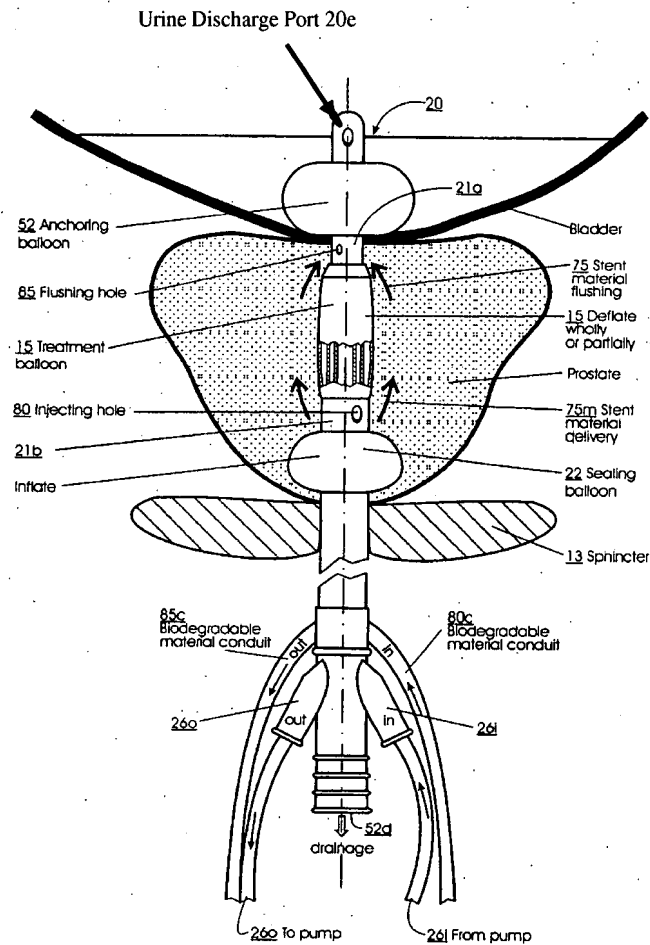


Fig. 10B

As shown in Fig. 10B of Cionata *et al.* and noted above, catheter 20 includes a urine discharge port 20e that is in fluid communication with a urine discharge or drainage channel 52d that allows urine to drain from the bladder through the catheter 20 while the catheter is in the subject. As the urine can freely flow out of the bladder through the urine discharge port 20e, balloons 15 and 52 do not cause the pressure to increase in the bladder. For the balloons to increase the pressure in the bladder, the flow of urine would have to be blocked or impeded. However, the urine can freely flow out of the bladder due to the pressure of urine discharge port

20e. Accordingly, Cionata *et al.* fails to disclose artificially increasing pressure in a urinary tract of at least one kidney of the patient as claimed by the applicant.

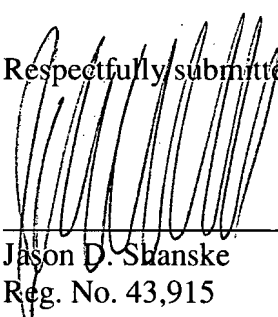
Additionally, Cionata *et al.* fails to disclose reducing a renal function of the kidney by maintaining the increased pressure as claimed by the applicant. Nowhere does Cionata *et al.* disclose anything regarding the operation of the kidneys. Cionata *et al.* is solely directed to an artificial bladder to enable a patient to urinate. As Cionata *et al.* fails to disclose maintaining the increased pressure, Cionata *et al.* also fails to disclose reducing a renal function of the kidney as claimed by the applicant.

Accordingly, independent claims 1 and 45, and their respective dependent claims, are patentable over Cionata *et al.*, either alone or in combination with Donald for at least the above reasons.

Each of the Examiner's rejections has been addressed or traversed. Accordingly, it is respectfully submitted that the application is in condition for allowance. Early and favorable action is respectfully requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts at (781) 890-5678.

Respectfully submitted,



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